APPENDIX A. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name, Address, Phone and Fax Number of the Applicant

Broncus Technologies, Inc.
1400 N. Shoreline Boulevard, Building A, Suite 8
Mountain View, CA 94043
Telephone: (650) 428-1600
Fax: (650) 428-1542

Contact Person

Timothy R. Williams
Director, Regulatory and Clinical Affairs

Date Summary was Prepared

December 22, 2000

Trade Name

Exhale Doppler System

Classification Number and Name

Class II, 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System

Class II, 21 CFR 892.1570, Diagnostic Ultrasound Transducer

Device Description

The *Exhale* Doppler System consists of a Doppler Processing Unit (DPU) and a Doppler Probe containing an ultrasonic transducer probe. The DPU receives standard 120V or 240V input and produces 8 MHz ultrasound output. The Doppler Probe is designed to detect blood flow in upper airways and the tracheobronchial tree through a bronchoscope and connects to the front panel of the DPU.

Intended Use

The *Exhale* Doppler System detects blood flow in the upper airways and tracheobronchial tree through a bronchoscope.

Substantial Equivalence

The *Exhale* Doppler System is substantially equivalent to the Olympus UM-2R/3R Ultrasonic Probe and ancillary equipment (K982323, and the IMEX StethoDop (K973336) with respect to intended use, method of introduction, method of operation, safety, and materials.

Safety

The *Exhale* Doppler System consisting of an Doppler Processing Unit, and a Doppler Probe containing an ultrasonic transducer were designed, and tested in compliance with International Standard IEC 60601-1. The *Exhale* Doppler System meets the requirements of the FDA's 510(k) Diagnostic Ultrasound Guidance for 1997 for a Track 1 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2001

Broncus Technologies, Inc.
C/O Mark Job, 510(k) Program Manager
TUV Product Service
1775 Old Highway 8 N.W.
Suite 104
NEW BRIGHTON MN 55112-1891

Re: K010649
Trade Name: Exhale™ Doppler System
Regulatory Class: II
Product Code: 21 CFR 892.1550/90 IYN
Dated: March 2, 2001
Received: March 5, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Exhale™ Doppler System, as described in your premarket notification:

Transducer Model Number:

ETS-30

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action.

In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded. The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David C. Segmon

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K010649

4.3 Diagnostic Ultrasound Indications For Use Form

System: *Exhale* Doppler System
Transducer: Model ETS -30

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal				N[a]			
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: N[a]: Intraluminal ultrasound for upper airways and tracheobronchial tree.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

David C. Segmn Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010649

NA II

SKS

510(k) Number (if known): K010649

Device Name: The *Exhale* Doppler System

Indications for Use: The *Exhale* Doppler System is designed to detect blood flow in the upper airways and tracheobronchial tree through a bronchoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010649